

Message Text

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PAGE 01 STATE 190705
ORIGIN HEW-06

INFO OCT-01 ARA-14 EUR-12 EA-12 IO-14 ISO-00 OES-09
PA-02 /070 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:VO
APPROVED BY OES/ENP/EN: WJWALSH, III
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EUR/CE:JHURLEY,JR
EA/J:EFEATHERSTONE
ARA/MEX BITTNER

-----125789 281556Z /43

P 281523Z JUL 78
FM SECSTATE WASHDC
TO AMEMBASSY BERN PRIORITY
AMEMBASSY TOKYO PRIORITY
AMEMBASSY MEXICO PRIORITY
INFO USMISSION GENEVA PRIORITY

UNCLAS STATE 190705

E.O. 11652:N/A

TAGS: OGEN, ETRD, EIND, TBIO, SZ, JA, MX

SUBJECT:FIR; IWITIATED DEVICE RECALL (T-123-8)

1. FDA ADVISES OF THE FOLLOWING A ESTHESIA DEVICE RECALL:
PRODUCT INVOLVED - ;ODEL 300 ANESTHESIA VENTILATO0, A
MECHANICAL ANESTHESIA VENTILATOR

„ PROD'T IDENTIFICATION - BRAN;D NAME IS "HOSPAL' OR
'HARLAKE , HOWEVER, IN ALL INSTANCES THE LABEL SHOWS
MANUFACTURER AS HOSPAL MEDICAL CORPORATIO', 4100 EAST DRY
CREEK ROAD, DENVER, COLORADO 80122. MODEL NUMBER OF THE
VE;TILATOR IS MODEL 300. SERIAL NUMBERS BEING RECALLED
ARE 312-01201 THROUGH 312-01272 AND 210H THROUGH 229H.
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„ MANUFACTURER/RECALLING FIRM - HOSPAL MEDICAL CORPORATIO',
EAST DRY CREEK ROAD, DENVER, COLORADO 801,2

4. REASO; FOR RECALL - AUTO-CYCLING (UNCO'TROLLED RESP-
IRATORY CYCLE RATE) OF THE VENTILATOR MAY OCCUR DUE TO A
SHAFT W'ICH ;AY BECOME DISPLACED IN THE MAIN VALVE. THIS

DEFECT WAS TRACED TO IMPROPER TAPERING OF THE HOLE IN WHICH THE SHAFT IS SEATED IN A SINGLE LOT OF THE MAIN VALVE SUB-ASSEMBLY. THE VALVE IS ALSO MANUFACTURED BY HOSPAL, IN DENVER. FIRM LEARNED OF THE PROBLEM THROUGH THE RETURN OF

2 VENTILATORS FROM AN ALBUQUERQUE, NM HOSPITAL. THE DEFECT BECOMES OBVIOUS WHEN AUTO-CYCLING OCCURS AT WHICH TIME THE MAIN VALVE MAY BE BY-PASSED. NO KNOWN DEATHS OR INJURIES ARE ASSOCIATED WITH THE PRODUCT. RECALL INITIATED 4/18/78 BY TELEPHONE FOLLOWED BY LETTERS AND TELEX ON 4/19/78.

5. POSTS ARE REQUESTED TO CHECK WITH FOREIGN CONSIGNEES (DISTRIBUTORS) TO DETERMINE IF THEY HAVE BEEN ADVISED OF RECALL AND PROCEDURES TO BE FOLLOWED AS INDICATED IN FIRM'S TELEX DATED 4/19/78. ANY QUESTIONS WITH REGARD TO RECALL SHOULD BE REFERRED DIRECTLY TO FIRM.

6. FOREIGN CONSIGNEES AS SUPPLIED TO FDA BY FIRM AND SERIAL NUMBERS OF DEVICES INVOLVED AS FOLLOWS:

HOSPAL BASEL	HOSPAL JAPAN
MISSION STRASSE 6Z	16TH KOWA BUILDING ANNEX
CH 4055	9-20 AKASAK 1
BASEL, SWITZERLAND	MINATO-KU, TOKYO
JAPAN	

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S RIAL NUMBER OF UNITS:

SERIAL NUMBER OF UNITS:

31201202	
31201204	31202170
31201214	31201260
31201207	31201254
31201210	31201253
31201211	31201229
31201209	31201225
31201218	31201226
31201208	31201219
31201222	
31201215	
31201217	
31201216	
31201221	

HARRY MAZAL S.A.
SULLIVAN 119
MEXICO 4, D.F. MEXICO

SERIAL NUMBER OF UNITS:

31201266

31201249 CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 28 jul 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE190705
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:VO
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780310-0409
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t1978078/aaaaagyv.tel
Line Count: 119
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: ab7fe378-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
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Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2070192
Secure: OPEN
Status: NATIVE
Subject: FIR; IWITIATED DEVICE RECALL (T-123-8)
TAGS: OGEN, ETRD, EIND, TBIO, SZ, JA, MX, FDA
To: BERN TOKYO MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/ab7fe378-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
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